REMARKS

Applicants' representatives thank Examiner Eileen O'Hara and Practice Specialist Paula Hutzell for the interview of October 11, 2001.

Claims 24-88, and 102-131 are currently pending. Claims 46 and 61 have been amended. Applicants reserve the right to pursue the subject matter of claims 46 and 61 as filed (i.e., as the claims read prior to the amendments requested herein). Claims 141-205 and 219-247 have been cancelled without prejudice. Applicants reserve the right to pursue the subject matter of the cancelled claims in related applications.

The Claimed Invention is Novel under 35 USC §102(e) and 103(a)

The Examiner has maintained the rejection of claims 24-29, 31, 33, 35-40, 42, 44, 46-55, 57, 59, 61-70, 72, 74, 76-83, 85, 87, 89-96, 98, 100, 102-111, 113, 115, 117, 118, 120, 122, 124-126, 128, 130, 206, 208, 209, 211-213, 215, 217, 219-224, 226, 227, 229, 231, 233, 234, 236, 238, 240-242, and 246 under 35 U.S.C. §102(e) as being anticipated by Emery et al., U.S. Patent Number 5,885,800 filed February 4, 1997 and granted March 23, 1999.

The Examiner has maintained the rejection of claims 32, 43, 73, 86, 99, 114, 121, 129, 216, 230, 237, and 245 under 35 U.S.C. §103(a) for alleged obviousness over Emery et al., U.S. Patent Number 5,885,800 filed February 4, 1997 and granted March 23, 1999, in view of U.S. Patent Number 4, 847,325 to Shadle et al., granted on July 11, 1989.

The Examiner has maintained the rejection of claims 30, 34, 41, 45, 56, 60, 71, 75, 84, 88, 97, 101, 112, 116, 119, 121, 123, 127, 131, 214, 218, 228, 232, 235, 239, 243, and 247 under 35 U.S.C. §103(a) for alleged obviousness over Emery et al., U.S. Patent Number 5,885,800 filed February 4, 1997 and granted March 23, 1999, in view of U.S. Patent Number 5,985,614 to Rosen et al., granted on November 16, 1999.

In Applicants' initial response to these rejections, Applicants perfected their claim to priority in the instant application so that the instant application would have an effective filing date prior to that of Emery et al, thereby obviating the Examiner's 102 and 103 rejections. The Examiner acknowledged Applicant's priority claim but contends that

> "...the provisional application [60/035,496] fails to provide a patentable utility for the polypeptides, and therefore one of skill in the art would not have known how to use the polypeptides. At the time of filing of the provisional application there was no disclosed activity or function of the polypeptides, and therefore

> fails to provide adequate support under 35 U.S.C. §112 for this application. Therefore the effective filing date of the instant application is January 13, 1998..." (Paper No. 17, page 6, lines 8-13).

Applicants respectfully, yet emphatically, disagree.

The 60/035,496 Application Discloses a Patentable Utility for the Claimed Polypeptides

The claimed polypeptides are useful, for example, in the treatment of graft vs. host disease. This utility is clearly disclosed in the 60/035,496 specification which discloses at page 7, lines 14-22 (page 8, lines 28 to page 9 line 7 of the instant application):

> The invention also provides for pharmaceutical compositions comprising TNFR polypeptides, particularly human TNFR polypeptides, which may be employed, for instance, to treat infectious disease including HIV infection, endotoxic shock, cancer, autoimmune diseases, graft vs. host disease, acute graft rejection, chronic graft rejection, neurodegenerative disorders, myelodysplastic syndromes, ischemic injury (e.g., ischemic cardiac injury), toxin-induced liver disease, septic shock, cachexia and anorexia.

This application is therefore entitled to the benefit of the filing date of the 60/035,496 application because the invention, including an asserted utility, is adequately described under 35 U.S.C. §112.

This utility has been confirmed, for example, by Zhang et al. (enclosed) who show that TR6-Fc treatment reduces splenomegaly in a murine model of graft vs. host disease.

The 60/035,496 Application Discloses at Least as Much as the Later Filed 5,885,800 Patent to Emery et al.

More importantly, Applicants disclosure of this patentable utility (while meeting all applicable legal standards) is, at the very least, as good as the disclosure by the Emery et al. reference. A typical example of the utility disclosed by Emery et al. is found in column 2, lines 39-47:

> Another aspect of the invention relates to methods for using such TR4 polypeptides and polynucleotides. Such uses include the treatment of chronic and acute inflammation, arthritis, septicemia, autoimmune diseases (eg inflammatory bowel disease, psoriasis), transplant rejection, graft vs. host disease, infection, stroke, ischemia, acute respiratory disease syndrome, restenosis, brain injury, AIDS, Bone diseases, cancer (eg

lymphoproliferative disorders), atherosclerosis, and Alzheimers disease, among others.

According to the Examiner, the Emery et al. reference is a valid patent worthy of its 102(e) date—a date only a valid patent can attain as a piece of prior art under the laws applying to this patent (i.e., before the effective date of the American Inventors Protection Act of 1999). Thus, according to the Examiner, the invention disclosed therein must have an adequate utility under 35 U.S.C. §101. Applicants' priority application discloses at least as much as the later filed Emery et al. reference. Therefore, it follows that Applicants' claimed invention also has a utility under 35 U.S.C. §101.

For the Patent Office, on the one hand, to accord Emery et al. a 102(e) date as a valid patent, and on the other hand, to deny Applicants a priority date behind this reference - despite the fact that Applicants disclose at this earlier date at least as much as Emery - places Applicants in a "Catch 22." This paradox is entirely the product of the Patent Office Utility Guidelines announced after the filing of either the instant priority application or Emery et al., and their current application (an inaccurate one at that) to this particular application.

Applicants emphasize that the asserted utility in the instant application is adequate under all applicable authority. At the very least, Applicants' priority application contains an assertion of utility, unlike the situation in the chief case on utility, *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), in which no utility was asserted at all. Furthermore, Applicants' asserted utility is a specific, substantial and credible utility and not a "throw away" utility (such as using a composition for landfill) as defined in the current United States Patent and Trademark Office's Utility Guidelines.

In sum, Applicants disclosed at least as much as the applicants of Emery et al. did, and at an earlier date. To deny Applicants a patent for the instant invention over Emery would be a gross and unreasonable inequity (as well as unjustified under 35 U.S.C. §101). Thus, Applicants respectfully request that the 102(e) and 103(a) rejections, all of which hinge on the Emery et al., reference be withdrawn.

The Claimed Invention is Adequately Enabled under 35 USC §112, First Paragraph

The Examiner rejects claims 46-75 and 141-192 under 35 U.S.C. § 112, first paragraph, for allegedly failing to enable one of skill in the art to make and/or use a polypeptide sequence comprising the amino acid sequence of SEQ ID NO:4 or a polypeptide

comprising an amino acid sequences 90% or 95% identical to SEQ ID NO:2 or 4 commensurate in scope with the claims.

This rejection has been obviated by Applicants' amendments to the claims. Applicants have amended claims 46 and 61 such that they recite that the claimed polypeptides bind Fas ligand. Applicants note that the Examiner indicated in a personal interview that such amendment would overcome the enablement rejection (see Interview Summary, Paper No. 18). Therefore, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants respectfully request that the amendments and remarks above be entered and made of record in the file history of the instant application. Applicants believe that all rejections have been overcome or obviated and that the claims are in condition for allowance. A Notice of Allowance is earnestly solicited. Should any additional fees be deemed necessary, please charge such fees to Deposit Account No. 08-3425.

Respectfully submitted,

Date: NOVEMBER 20, 2001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gentz et al. Art Unit: 1646
Application Serial No.: 09/518,931 Examiner: O'Hara, Eileen
Filed: March 3, 2000 Attorney Docket No.: PF454P1
For: Tumor Necrosis Factor Receptors 6alpha & 6beta

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amendments are shown in boldfaced text. Deletions are indicated by strikeout and insertions are indicated by underlining.

In the Claims:

Claims 141-205 and 219-247 have been cancelled without prejudice.

Claims 46 and 61 has been amended as follows:

46. (New) An isolated polypeptide comprising an amino acid sequence 90% or more identical to an amino acid sequence selected from the group consisting of:

(a) amino acid residues 1 to 300 of SEQ ID NO:2;

(b) amino acid residues 2 to 300 of SEQ ID NO:2;

(c) amino acid residues 31 to 300 of SEQ ID NO:2; and

(d) amino acid residues 31 to 283 of SEQ ID NO:2.

wherein said polypeptide binds Fas ligand.

61. (New) An isolated polypeptide comprising an amino acid sequence 90% or more identical to an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 97810.

(b) the amino acid sequence of the full-length polypeptide excluding the amino-terminal methionine encoded by the cDNA contained in ATCC Deposit No 97810.

(c) the amino acid sequence of the mature polypeptide encoded by the cDNA contained in ATCC Deposit No. 97810; and

(d) the amino acid sequence of the extracellular domain of the polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97810.

wherein said polypeptide binds Fas ligand.